

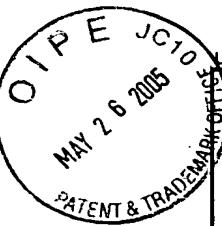
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PTO/SB/21 (09-04)

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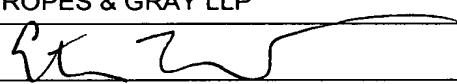
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		Application Number	10/641376
		Filing Date	August 14, 2003
		First Named Inventor	Michael S. H. Chu
		Art Unit	3739
		Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	11	Attorney Docket Number	MIY-P01-027

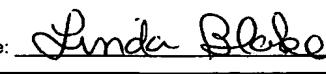
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### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	ROPES & GRAY LLP		
Signature			
Printed name	Erika Takeuchi		
Date	May 26, 2005	Reg. No.	55,661

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Dated: May 26, 2005 Signature: Linda Blake  
(Linda Blake)

Docket No.: MIY-P01-027  
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Chu et al.

Confirmation No.: 9640

Application No.: 10/641376

Art Unit: 3739

Filed: August 14, 2003

Examiner: Not Yet Assigned

For: SPACER FOR SLING DELIVERY SYSTEM

May 26, 2005

**INFORMATION DISCLOSURE STATEMENT (IDS)**

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Commissioner for Patents  
P.O. Box 1450  
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Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

Applicants have become aware of the document, cited in an International Search Report issued January 16, 2004 during the prosecution of international application no. PCT/US03/25451, which corresponds to the above referenced application, and in accordance with 37 CFR 1.97(b)(2), (b)(3) and (e)(1), hereby submit(s) these documents for the Examiner's consideration. These documents are also cited on the enclosed PTO Form SB/08, and a copy of the International Search Report and each document cited thereon are enclosed as well.

This statement is not to be interpreted as a representation that the cited documents are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any document herein be construed *per se* as a representation that such document is prior art. Moreover, Applicants understand the Examiner will make an independent evaluation of the cited documents.

A copy of each reference on the PTO/SB/08 is attached, except the U.S. Patents.

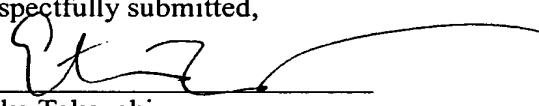
In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

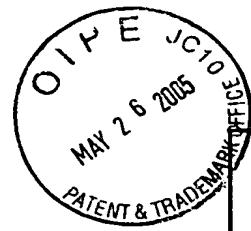
The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. MIY-P01-027. A duplicate copy of this paper is enclosed.

Dated: May 26, 2005

Respectfully submitted,

By   
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Substitute for form 1449A/B/PTO				<b>Complete If Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				Application Number	10/641376
Sheet	1	of	5	Filing Date	August 14, 2003
				First Named Inventor	Michael S. H. Chu
				Art Unit	3739
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	MIY-P01-027

<b>U.S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
AA	US-5,250,033		10-05-1993	Evans et al.	
AB	US-5,256,150		10-26-1993	Quiachon et al.	
AC	US-5,368,595		11-29-1994	Lewis et al.	
AD	US-5,456,722		10-10-1995	McCleod et al.	
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Examiner Signature	Date Considered
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Substitute for form 1449A/B/PTO				<b>Complete If Known</b>	
				Application Number	10/641376
				Filing Date	August 14, 2003
				First Named Inventor	Michael S. H. Chu
				Art Unit	3739
				Examiner Name	Not Yet Assigned
Sheet	2	of	5	Attorney Docket Number	MIY-P01-027

AT1	US-2,917,878	12-22-1959	Edwin et al.	
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AA2	US-6,110,101	08-29-2000	Tihon, C. et al.	
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AH2	US-2002/015648	10-24-2002	Gellman, B. et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			
BA	DE 8203923		04-07-1983	Henkel KGAA	
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BE	WO 02/28315		04-11-2002	American Med System	
BF	DE-20204669		09-11-2003	Aesculap AG & Co.	

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NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	CA	BAYER et al., "A New Approach to Primary Strengthening of Colostomy with Marlex® Mesh to Prevent Paracolostomy Hernia," <i>Surgery, Gynecology &amp; Obstetrics</i> , December 1986, Vol. 163, pp. 579-580.			
	CB	DELORME., "La bandelette trans-obturatrice: un procede mini-invasif pour traiter l'incontinence urinaire d'effort de la femme," <i>Progres en Urologie</i> , Vol. 11, 2001, pp. 1306-1313. (English summary therein)			

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				Art Unit	3739
				Examiner Name	Not Yet Assigned
Sheet	3	of	5	Attorney Docket Number	MIY-P01-027

CC	FIANU et al., "Absorbable Polyglactin Mesh for Retropubic Sling Operations in Female Urinary Stress Incontinence," <i>Gynecol. Obstet. Invest.</i> Vol. 16, pp. 45-50 (1983).
CD	GIESY et al., "Ureteral Instrumentation: A New System for Continued Access via a Safety Guidewire," <i>The Journal of Urology</i> , No. 4, Part 2, April 1988, p. 282A.
CE	GITTES et al., No-Incision Pubovaginal Suspension for Stress Incontinence, <i>Journal of Urology</i> , vol. 138, Sep. 1987, pp. 568-570.
CF	HAAB et al. "Feasibility of Outpatient Percutaneous Bladder Neck Suspension Under Local Anesthesia," <i>Urology</i> , Vol 50, 1997, pp. 585-587.
CG	JACQUETIN, B., "Utilisation du TVT dans la chirurgie de l'incontinence urinaire féminine", <i>J Gynecol Obstet Biol Reprod</i> 2000, Vol. 29, pp. 242-247. (English summary therein)
CH	KERSEY et al., "The Gauze Hammock Sling Operation in the Treatment of Stress Incontinence," <i>British Journal of Obstetrics and Gynecology</i> , Vol. 90, pp. 945-949, October 1983.
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CJ	NORRIS et al, "Use of Synthetic Material in Sling Surgery: A Minimally Invasive Approach," <i>Journal of Endourology</i> , Vol. 10, No.3, June 1996.
CK	PETROS, P., "An Integral Theory of Bladder Neck Opening, Closure and Urinary Incontinence in the Female", <i>International Journal of Gynecology &amp; Obstetrics</i> , XXIII World Congress of Gynaecology and Obstetrics (FIGO) 1991.
CL	PETROS et al., "An Integral Theory and Its Method for the Diagnosis and Management of Female Urinary Incontinence," <i>Scandinavian Journal of Urology and Nephrology</i> , Supplement 153, 1993, pp. 1-93.
CM	PETROS, "Ambulatory Surgery for Urinary Incontinence and Vaginal Prolapse," <i>The Medical Journal of Australia</i> , July 1994, Vol. 161, pp. 171-172.
CN	PETROS et al., "Urethral Pressure Increase on Effort Originates From Within the Urethra, and Continence From Mulculovaginal Closure", <i>Neurourology and Urodynamics</i> , 1995, pp. 337-350.
CO	PETROS, "The Intravaginal Slingplasty Operation, a Minimally Invasive Technique for Cure of Urinary Incontinence in the Female," <i>Aust. And N.Z. Journal of Obstetrics and Gynecology</i> , 1996, Vol. 4, pp. 453-461.
CP	PETROS, "Medium-term Follow-up of the Intravaginal Slingplasty Operation Indicates Minimal Deterioration of Urinary Continence With Time", <i>Aust. And N.Z. Journal of Obstetrics and Gynecology</i> , 1999, Vol. 39, pp. 354-356.
CQ	RAZ, "Modified Bladder Neck Suspension for Female Stress incontinence," <i>Urology</i> , January 1981, Vol. 17, No. 1, pp. 82-85.

Examiner Signature	Date Considered
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				Examiner Name	Not Yet Assigned
Sheet	4	of	5	Attorney Docket Number	MIY-P01-027

	CR	RAZ et al. "Fascial Sling to Correct Male Neurogenic Sphincter Incompetence: The McGuire/Raz Approach," The Journal of Urology, Vol. 139, 1988, pp. 528-531.	
	CS	RAZ et al. "Vaginal Wall Sling" The Journal of Urology, Vol. 141, No. 1, January 1989, pp. 43-46.	
	CT	STAMEY, "Endoscopic Suspension of the Vesical Neck for Urinary Incontinence," Surgery, Gynecology & Obstetrics, April 1973, Vol. 136, No. 4, pp. 547-554	
	CU	STAMEY, "Endoscopic Suspension of the Vesical Neck for Urinary Incontinence in Females," Ann. Surg., October 1980, Vol. 192, No. 4, pp. 465-471.	
	CV	STAMEY, "Endoscopic Suspension of the Vesical Neck," Stanton, Tanagho (eds). Surgery of Female Incontinence. Springer-Verlag, Berlin; 1986, pp. 115-132.	
	CW	STASKIN, "Sling Surgery for the Treatment of Female Stress Incontinence," Problems in Urology, Vol. 5, No. 1, March 1991, pp. 106-122.	
	CX	STASKIN et al., "The Gore-tex sling procedure for female sphincteric incontinence: indications, technique, and results," World Journal of Urology, Vol. 15, No. 5, 1997, pp. 295-299.	
	CY	SUSSMAN et al., "The Raz Bladder Neck Suspension: Five-Year Experience", The Journal of Urology, 1993, Vol. 145, p. 223A.	
	CZ	ULMSTEN et al., "Connective Tissue Factors in the Aetiology of Female Pelvic Disorders", Ann. Med., December 1990, Vol. 22, No. 6, p. 3.	
	CA1	ULMSTEN et al., "Surgery for Female Urinary Incontinence", Current Opinion in Obstetrics & Gynecology, 1992, Vol. 4, No. 3, pp. 456-462.	
	CB1	ULMSTEN, et al, "Intravaginal Slingplasty", Zentralblatt für Gynäkologie, 1994, pp. 398-404.	
	CC1	ULMSTEN et al., "Intravaginal Slingplasty (IVS): An Ambulatory Surgical Procedure for Treatment of Female Urinary Incontinence", Scandinavian Journal of Urology and Nephrology, March 1995, Vol. 29, No. 1, pp. 75-82.	
	CD1	ULMSTEN et al., "An Ambulatory Surgical Procedure Under Local Anesthesia for Treatment of Female Urinary Incontinence", The International Urogynecology Journal, 1996, pp. 81-86.	
	CE1	ULMSTEN et al., "A Multicenter Study of Tension-Free Vaginal Tape (TVT) for Surgical Treatment of Stress Urinary Incontinence", International Urogynecology Journal, 1998, Vol. 9, No. 4, pp. 210-213.	
	CF1	ULMSTEN et al., "A Three-Year Follow Up of Tension Free Vaginal Tape for Surgical Treatment of Female Stress Urinary Incontinence", British Journal of Obstetrics and Gynaecology, April 1999, Vol. 106, pp. 345-350.	
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Examiner Signature	Date Considered
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				Art Unit	3739
				Examiner Name	Not Yet Assigned
Sheet	5	of	5	Attorney Docket Number	MIY-P01-027

	CH1	ULMSTEN, U., "The Basic Understanding and Clinical Results of Tension-Free Vaginal Tape for Stress Urinary Incontinence", Der Urologe [A] 4-2001, pp. 269-273.	
	CJ1	Copy of International Search Report from International Application No. PCT/US03/25451 dated January 16, 2004	

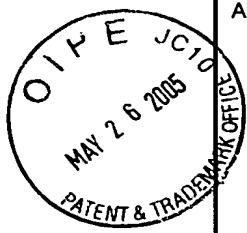
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Application No. (if known): 10/641376

Attorney Docket No.: MIY-P01-027



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